Senate

General Assembly

File No. 693

January Session, 2003

Substitute Senate Bill No. 494

Senate, May 14, 2003

The Committee on Appropriations reported through SEN. HARP of the 10th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING ELECTRONIC MONITORING OF CONTROLLED SUBSTANCE PRESCRIPTIONS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 21a-254 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2006*):

(a) The Commissioner of Consumer Protection, after investigation and hearing, may by regulation designate certain substances as restricted drugs or substances by reason of their exceptional danger to health or exceptional potential for abuse so as to require written records of receipt, use and dispensation, and may, after investigation and hearing, remove the designation as restricted drugs or substances from any substance so previously designated.

(b) Each physician, dentist, veterinarian or other person who is authorized to administer or professionally use schedule I substances shall keep a record of such schedule I substances received by **[**him**]**

such person and a record of all such schedule I substances administered, dispensed or professionally used by [him] such person. The record of schedule I substances received shall in each case show the date of receipt, the name and address of the person from whom received and the kind and quantity of schedule I substances received. The record of all schedule I substances administered, dispensed or otherwise disposed of shall show the date of administering or dispensing, the name and address of the person to whom, or for whose use, or the owner and species of animal for which, the substances were administered or dispensed and the kind and quantity of substances.

(c) Practitioners obtaining and dispensing controlled substances shall keep a record of all such controlled substances, received and dispensed by them in accordance with the provisions of subsections (f) and (h) of this section.

(d) Manufacturers and wholesalers shall keep records of all controlled substances, compounded, mixed, cultivated or grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section.

(e) Pharmacies, hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision, clinics, infirmaries, free-standing ambulatory surgical centers and laboratories shall keep records of all controlled substances, received and disposed of by them in accordance with the provisions of subsections (f) and (h) of this section, except that hospitals and chronic and convalescent nursing homes using a unit dose drug distribution system may instead keep such records in accordance with the provisions of subsections (g) and (h) of this section, and except that hospitals and free-standing ambulatory surgical centers shall not be required to maintain separate disposition records for schedule V controlled substances or records of administering of individual doses for ultra-short-acting depressants, including, but not limited to, Methohexital, Thiamylal and Thiopental.

(f) The form of record to be kept under subsection (c), (d) or (e) of

this section shall in each case show the date of receipt, the name and address of the person from whom received, and the kind and quantity of controlled substances received, or, when applicable, the kind and quantity of controlled substances produced or removed from process of manufacture and the date of such production or removal from process of manufacture; and the record shall in each case show the proportion of controlled substances. The record of all controlled substances sold, administered, dispensed or otherwise disposed of shall show the date of selling, administering or dispensing, the name of the person to whom or for whose use, or the owner and species of animal for which, the substances were sold, administered or dispensed, the address of such person or owner in the instance of records of other than hospitals, chronic and convalescent nursing homes, rest homes with nursing supervision and infirmaries, and the kind and quantity of substances. In addition, hospital and infirmary records shall show the time of administering or dispensing, the prescribing physician and the nurse administering or dispensing the substance. Each such record of controlled substances shall be separately maintained apart from other drug records and kept for a period of three years from the date of the transaction recorded.

(g) Hospitals using a unit dose drug distribution system shall maintain a record noting all dispositions of controlled substances from any area of the hospital to other hospital locations. Such record shall include, but need not be limited to, the name, form, strength and quantity of the drug dispensed, the date dispensed and the location within the hospital to which the drug was dispensed. Such dispensing record shall be separately maintained, apart from other drug or business records, for a period of three years. Such hospital shall, in addition, maintain for each patient a record which includes, but need not be limited to, the full name of the patient and a complete description of each dose of medication administered, including the name, form, strength and quantity of the drug administered, the date and time administered and identification of the nurse or practitioner administering each drug dose. Entries for controlled substances shall be specially marked in a manner **[**which**]** that allows for ready

identification. Such records shall be filed in chronological order and kept for a period of three years.

(h) A complete and accurate record of all stocks of controlled substances on hand shall, on and after July 1, 1981, be prepared biennially within four days of the first day of May of the calendar year, except that a registrant may change this date provided the general physical inventory date of such registrant is not more than six months from the biennial inventory date, and kept on file for three years; and shall be made available to the commissioner or **[**his**]** the commissioner's authorized agents. The keeping of a record required by or under the federal Controlled Substances Act, or federal food and drug laws, containing substantially the same information as is specified above, shall constitute compliance with this section, provided each record shall in addition contain a detailed list of any controlled substances lost, destroyed or stolen, the kind and quantity of such substances and the date of the discovery of such loss, destruction or theft and provided such record shall be made available to the commissioner or **[**his**]** the commissioner's authorized agents. All records required by this chapter shall be kept on the premises of the registrant and maintained current and separate from other business records in such form as to be readily available for inspection by the authorized agent at reasonable times. The use of a foreign language, codes or symbols to designate controlled substances or persons in the keeping of any required record is not deemed to be a compliance with this chapter.

(i) Whenever any record is removed by a person authorized to enforce the provisions of this chapter or the provisions of the state food, drug and cosmetic laws for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of three years.

(j) (1) The Commissioner of Consumer Protection shall implement a program to collect, by electronic means, prescription information for schedule II, III, IV and V controlled substances, as defined in

subdivision (9) of section 21a-240, that are dispensed by pharmacies and outpatient pharmacies in hospitals or institutions. The program shall be designed to provide information regarding the prescription of controlled substances in order to prevent the improper or illegal use of the controlled substances, and shall not infringe on the legitimate prescribing of a controlled substance by a prescribing practitioner acting in good faith and in the course of professional practice.

(2) Each pharmacy and each outpatient pharmacy in a hospital or institution shall report to the commissioner, at least once monthly, by electronic means or, if a pharmacy does not maintain records electronically, in a format approved by the commissioner, the following information for all controlled substance prescriptions dispensed by such pharmacy or outpatient pharmacy: (A) The prescription number; (B) an indication of whether the prescription dispensed was a new prescription or a refill; (C) the date of dispensing; (D) if available in the system utilized by the pharmacy or outpatient pharmacy, the time of the dispensing of the prescription; (E) the name, address and date of birth or other designation of age of the person or animal for whom the prescription was dispensed; (F) the National Drug Code (NDC) of the controlled substance dispensed; (G) the quantity of the controlled substance dispensed; (H) the number of days' supply of the controlled substance dispensed; (I) the prescribing practitioner's federal Drug Enforcement Agency (DEA) registration number; and (J) the federal Drug Enforcement Agency (DEA) number of the pharmacy dispensing the controlled substance.

(3) Controlled substance prescription information reported to the commissioner pursuant to subdivision (2) of this subsection shall not be disclosed, except as authorized pursuant to the provisions of sections 21a-240 to 21a-283, inclusive. Nothing in this subsection shall be construed to prevent the commissioner from contracting with a vendor for purposes of electronically collecting such controlled substance prescription information, provided the information is maintained in a confidential manner by the vendor and is maintained in accordance with the general statutes.

(4) The commissioner shall provide, upon request, controlled substance prescription information obtained in accordance with this section to the following: (A) A prescribing practitioner who is treating or has treated a specific patient, provided the information is obtained for purposes related to the treatment of the patient, including the monitoring of controlled substances obtained by the patient; (B) a prescribing practitioner with whom a patient has made contact for the purpose of seeking medical treatment, provided the request is accompanied by a written consent, signed by the prospective patient, for the release of controlled substance prescription information; (C) a pharmacist who is dispensing controlled substances for a specific patient, provided the information is obtained for purposes related to the scope of the pharmacist's practice and management of the patient's drug therapy, including the monitoring of controlled substances obtained by the patient. A request for controlled substance prescription information made by a prescribing practitioner or by a pharmacist must be submitted to the commissioner in writing or by facsimile transmission and must be signed by the prescribing practitioner or the pharmacist making the request. Requests for controlled substance prescription information made to the commissioner pursuant to this section shall not be disclosed, except as authorized pursuant to sections 21a-240 to 21a-283, inclusive, or sections 20-570 to 20-630, inclusive.

(5) The commissioner shall adopt regulations with the advice of the Prescription Drug Monitoring Working Group established pursuant to section 2 of this act, in accordance with chapter 54, concerning the reporting, evaluation, management and storage of electronic controlled substance prescription information.

Sec. 2. (NEW) (*Effective October 1, 2006*) The Commissioner of Consumer Protection shall appoint a Prescription Drug Monitoring Working Group to advise the commissioner on the implementation of the electronic prescription drug monitoring program established pursuant to subsection (j) of section 21a-254 of the general statutes, as amended by this act. The working group shall include, but not be

limited to: (1) An internal medicine specialist; (2) an oncologist; (3) an advanced practice registered nurse; (4) a representative from an acute care hospital; (5) a state police officer; (6) a local police chief; (7) a representative from the Division of Criminal Justice; (8) a representative from a hospice organization; (9) a pain management specialist; and (10) a pharmacist.

This act shall take effect as follows:	
Section 1	*October 1, 2006*
Sec. 2	*October 1, 2006*

APP *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Type	FY 07	FY 08
Consumer Protection, Dept.	GF - Future Cost	Up to $150,000	100,000

Note: GF=General Fund

Municipal Impact: None

Explanation

Commencing on October 1, 2006, this bill would require the electronic submission of controlled substance prescriptions to the Commissioner of Consumer Protection in order to facilitate monitoring to prevent their improper or illegal use. It also establishes the Prescription Drug Monitoring Working Group and requires the commissioner to adopt regulations, with the advice of the Prescription Monitoring Working Group, concerning the reporting, evaluation, management and storage of electronic controlled substance information.

Currently, the Department of Consumer Protection's Drug Control Agents have access to this information. However, the agents are required to go to the pharmacies in order to obtain the information. Since this bill requires the pharmacies to electronically transfer this information on a monthly basis, the department would need up to $150,000 start up costs in FY 07 to purchase the necessary software to implement the program using an outside vendor, and $100,000 each year, thereafter, for upkeep and maintenance.

Appointing a Prescription Drug Monitoring Working Group or the promulgation of regulations will necessitate additional budgetary resources.

OLR Bill Analysis
sSB 494

AN ACT CONCERNING ELECTRONIC MONITORING OF CONTROLLED SUBSTANCE PRESCRIPTIONS

SUMMARY:
This bill requires the consumer protection commissioner to establish a program to collect prescription information about Schedules II, III, IV, and V controlled substances from pharmacies. It requires the program to be designed to provide information about the prescription of these substances to prevent their improper or illegal use. It prohibits the program from infringing on legitimate prescriptions of controlled substances made in good faith and in the course of professional practice.

The bill (1) establishes the Prescription Drug Monitoring Working Group, (2) sets requirements for reporting, (3) prohibits disclosure of reported prescription information except as authorized by the law on dependency-producing drugs and this bill, and (4) requires the program to release reported information to certain prescribing practitioners and pharmacists. The bill requires the commissioner to adopt regulations with the advice of the working group on the reporting, evaluation, management, and storage of electronic controlled substance information.

EFFECTIVE DATE: October 1, 2006

PRESCRIPTION DRUG MONITORING WORKING GROUP

The working group must advise the commissioner on the implementation of the program. It must include:

1. an internal medicine specialist,

2. an oncologist,

3. an advanced practice registered nurse,

4. a representative from an acute care hospital,

5. a state police officer,

6. a local police chief,

7. a representative from the Division of Criminal Justice,

8. a representative from a hospice,

9. a pain management specialist, and

10. a pharmacist.

It may also include additional members.

REPORTING

The bill requires each pharmacy and outpatient pharmacy in a hospital or institution to report electronically at least once each month the following information for each dispensed controlled substance prescription:

1. prescription number;

2. whether the prescription was new or a refill;

3. dispensing date;

4. time of dispensing the prescription, if the pharmacy's system makes this possible;

5. patient's name, address, and date of birth or other designation of age;

6. National Drug Code of the dispensed controlled substance;

7. amount dispensed;

8. number of days supply;

9. prescribing practitioner's federal Drug Enforcement Agency

registration number; and

10. pharmacy's federal Drug Enforcement Agency number.

The bill allows pharmacies that do not keep records electronically to submit the reports in a format approved by the consumer protection commissioner.

RELEASE OF REPORTED INFORMATION

The bill requires the commissioner to provide controlled substance prescription information, on request, to the following:

1. a prescribing practitioner who is treating, or has treated, a specific patient, if the information is to be used in relation to the patient's treatment, including the monitoring of these drugs;

2. a prescribing practitioner who has been contacted by a prospective patient seeking medical treatment, if the request is accompanied by the patient's signed, written consent; and

3. a pharmacist who is dispensing controlled substances for a specific patient, if the information is being sought in relation to the pharmacist's scope of practice and management of the patient's drug therapy, including the monitoring of these drugs.

The bill requires information requests to be signed and written and allows them to be sent by facsimile transmission. The bill prohibits disclosure of such information requests, except as authorized under the law on dependency-producing drugs and the Pharmacy Practice Act. The bill provides that it may not be construed to prevent the commissioner from contracting with a vendor to operate the electronic reporting system, if the vendor keeps the information confidential.

BACKGROUND

Controlled Substances

Controlled substances are grouped in Schedules I through V, according to their decreasing tendency to promote abuse or dependency. Schedule I substances are the most strictly controlled because of their high potential for abuse. State and federal laws

authorize prescribing drugs on Schedules II through V; most Schedule I drugs do not have any approved medical use.

Legislative History

On April 9, the Senate referred the bill (File 56) to the Appropriations Committee, which reported a substitute bill on May 1 changing the effective date from October 1, 2004 to October 1, 2006.

COMMITTEE ACTION

General Law Committee

Joint Favorable Report
Yea 15 Nay 2

Appropriations Committee

Joint Favorable Substitute
Yea 38 Nay 10